Section A: KEY IDENTIFYING INFORMATION

A1. Study Identification Number ___ ___ - ___ ___ ___ ___ ___ - ___

Replaced by blinded ID

blind_id	Blinded ID

A2. Acrostic Identifier ___ ___ ___ ___ ___

Removed to protect privacy

A3. Study visit

STUDY VISIT 1 (Day 4) .....1 **(A4)**
STUDY VISIT 2 (Week 2).....2 **(A3a)**
STUDY VISIT 3 (Pre-Glenn).....3 **(A4)**
STUDY VISIT 4 (Restart) .....4 **(A3a)**
STUDY VISIT 5 (Age 10 mo).....5 **(A3a)**
STUDY VISIT 6 (Age 14 mo).....6 **(A4)**

VISIT	A3. Visit:

a. Visit completed at PHN Center? YES ..... 1 NO ..... 2 *(Do not complete B1-B3)*

VIS24CTR	[Added Version D] A3a. Visit completed at PHN center?

A4. Date of visit ___ ___ / ___ ___ / ___ ___ ___ ___
M M D D Y Y Y Y

Replaced by age at visit

visit_age	A4. <created var>Age at visit, days

A5. Date of form completion ___ ___ / ___ ___ / ___ ___ ___ ___
M M D D Y Y Y Y

Replaced by age at form completion

comp_age	A5. <created var>Age at form completion, days

A6. Name of person completing form _____ ___ ___ ___
PRINT FULL NAME INITIALS

Removed to protect privacy

Section B: CLINICAL ASSESSMENT

INSTRUCTIONS: If Measures 1 and 2 for questions B1, B2 and B3 differ by more than the stated amount in the "Difference" column, a third measurement must be taken.

	a. Measure 1	b. Measure 2	Difference	c. Measure 3
B1. Weight (kg)	___ ___ . ___ ___	___ ___ . ___ ___	**> 0.1 kg ➔**	___ ___ . ___ ___

WT1_FU	B1a. Weight: Measure 1 (kg)
WT2_FU	B1b. Weight: Measure 2 (kg)
WT3_FU	B1c. Weight: Measure 3, if |WT1_FU-WT2_FU|>0.1 (kg)
meanfuwt	<created var> Mean of all available follow-up weights (kg)

B2. Length (cm)	___ ___ . ___	___ ___ . ___	**> 1.0 cm ➔**	___ ___ . ___

HT1_FU	B2a. Length: Measure 1 (cm)
HT2_FU	B2b. Length: Measure 2 (cm)
HT3_FU	B2c. Length: Measure 3, if |HT1_FU-HT2_FU|>1.0 (cm)
meanfuht	<created var> Mean of all available follow-up lengths (cm)

B3. Head circumference (cm)	___ ___ . ___	___ ___ . ___	**> 0.2 cm ➔**	___ ___ . ___

HC1_FU	B3a. Head circumference: Measure 1 (cm)
HC2_FU	B3b. Head circumference: Measure 2 (cm)
HC3_FU	B3c. Head circumference: Measure 3, if |HC1_FU-HC2_FU|>0.2 (cm)
meanfuhc	<created var> Mean of all available follow-up head circumferences (cm)

Calculated WHO growth z-scores

_ZWEI	Weight-for-age z-score
_ZLEN	Length/height-for-age z-score
_ZWFL	Weight-for-length/height z-score
_ZBMI	BMI-for-age z-score
_ZHC	Head circumference-for-age z score
wazpct	<created var> Percentile for weight-for-age
lazpct	<created var> Percentile for length/height-for-age
bmizpct	<created var> Percentile for BMI-for-age
wlzpct	<created var> Percentile for weight-for-length/height
hczpct	<created var> Percentile for head circumference-for-age

B4. Systolic blood pressure ___ ___ ___ mmHg

FSBP	B4. Systolic BP (mmHg)

B5. Diastolic blood pressure ___ ___ ___ mmHg

FDBP	B5. Diastolic BP (mmHg)

B6. Mean blood pressure ___ ___ ___ mmHg

FMBP	B6. Mean BP (mmHg)

B7. How is blood pressure measured? AUSCULTATION 1
DYNAMAP 2

BPDEVICE	B7. How is blood pressure measured

B8. Oxygen saturation by pulse oximeter ___ ___ ___ % UNKNOWN ..... -8

a. Type of air ROOM AIR.....1 OXYGEN.....2

FO2SAT	B8. Oxygen saturation by pulse oximeter (%)
FAIRTYPE	B8a. Type of air

Section C: NON-STUDY MEDICATIONS

C1. Number of non-study medications patient is currently taking, including any he/she will receive a prescription for at this visit ___ ___ (0-10) (If 0, skip to **D1**)

FNUMMED	C1. Number of non-study medications patient is currently taking

Medication Code (See Code List D) **[Code required for data entry]**	**Medication Name Worksheet** **[Use this space to write name of drug]**
a. ___ ___ . ___ ___	
b. ___ ___ . ___ ___	
c. ___ ___ . ___ ___	
d. ___ ___ . ___ ___	
e. ___ ___ . ___ ___	
f. ___ ___ . ___ ___	
g. ___ ___ . ___ ___	
h. ___ ___ . ___ ___	
i. ___ ___ . ___ ___	
j. ___ ___ . ___ ___	

fmedcode	<created var> All non-study medications (Code List D)
fmedcode_0 - fmedcode_21	<created var> Non-study medication code (Code List D) (0)
FMEDNAME_0 - FMEDNAME_21	C1a-C1v. Specify other non-study medication (0)

Section D: ADVERSE EVENTS

D1. Adverse event since last study visit? YES..... 1 NO..... 2 **(E1a)**

Complete Form S200 for each event

AE_FU	D1. Adverse event since last study visit

a. Number of adverse event(s) ___ ___

NUMAE_FU	D1a. Number of adverse events

Section E: FEEDING REGIMEN

Feeding	a. Type of Feeding		b. Caloric Density	c. Daily Volume
	YES	**NO**		
E1. Bottle	1	2 **(E2a)**	___ .___ ___ Kcal/cc Unknown..... -8	___ ___ ___ ___ cc/day Unknown .....-8

FBOTTLE	E1a. Type of Feeding: Bottle
FBOTCAL	E1b. Caloric Density: Bottle (Kcal/cc)
FBOTVOL	E1c. Daily Volume: Bottle (cc/day)

Feeding	a. Type of Feeding		b. Caloric Density	c. Daily Volume
	YES	**NO**		
E2. Breast	1	2 **(E3i)**	___ .___ ___ Kcal/cc Unknown..... -8	___ ___ ___ ___ cc/day Unknown .....-8

FBREAST	E2a. Type of Feeding: Breast
FBRSTCAL	E2b. Caloric Density: Breast (Kcal/cc)
FBRSTVOL	E2c. Daily Volume: Breast (cc/day)

Feeding	a. Type of Feeding		b. Caloric Density	c. Daily Volume
	YES	**NO**		
E3. NG/GT				
i. Breast milk	1	2 **(E3ii)**	___ .___ ___ Kcal/cc Unknown..... -8	___ ___ ___ ___ cc/day Unknown .....-8

FNGBR	E3ia. Type of Feeding: Breast Milk
FNGBRCAL	E3ib. Caloric Density: NG/GT Breast milk (Kcal/cc)
FNGBRVOL	E3ic. Daily Volume: NG/GT Breast milk (cc/day)

Feeding	a. Type of Feeding		b. Caloric Density	c. Daily Volume
	YES	**NO**		
E3. NG/GT				
ii. Formula	1	2 **(E4)**	___ .___ ___ Kcal/cc Unknown..... -8	___ ___ ___ ___ cc/day Unknown .....-8

FNGF	E3iia. Type of Feeding: Formula
FNGFCAL	E3iib. Caloric Density: NG/GT Formula (Kcal/cc)
FNGFVOL	E3iic. Daily Volume: NG/GT Formula (cc/day)

Created feeding variables:

TOTCAL	<created var> Daily calories (Kcal/day)
Kcal_kg	<created var> Daily calories per kg (Kcal/day/kg)
Feedgrp	<created var> Feeding Mechanism

E4. Patient receiving solid foods? YES.....1 NO.....2 UNKNOWN....-8

SOLIDFD	E4. Patient receiving solid foods

Section F: SERUM FOR BNP

F1. If Study Visit 3 (Pre-Glenn) or 6 (Age 14 mo.), was a blood sample collected for the BNP Core Laboratory?

YES..... 1 **Complete Form S320**

NO 2

BNPSTORE	F1. Was blood sample collected for the BNP Core lab?

Section G: SERUM FOR GENOTYPING

G1. Did the parent/legal guardian sign the informed consent document for RAAS genotyping *at this visit*?

YES..... 1

NO (DECLINED) ..... 2 **(H1)**

UNDECIDED/NOT APPROACHED AT THIS VISIT.....-1 **(H1)**

GENOCNST	G1. Did parent/guardian sign genotyping consent at this visit?

G2. Did the parent/legal guardian provide written informed consent for future genotyping studies?

YES..... 1

NO (DECLINED) 2

FUTRCNST	G2. Did parent/guardian sign future genotyping informed consent

G3. Was a blood sample obtained for the Genetics Core Laboratory associated with this study visit?

YES .....1 **Complete Form S330**

NO.....2

BLDCOLL	G3. Was a blood sample obtained for the Genetics Core Lab

Section H: CARDIAC CATHETERIZATION

H1. If Study Visit 3 (Pre-Glenn), was a cardiac catheterization completed (not protocol mandated)?

YES .....1 **Complete Form S108**

NO 2

PREGCATH	H1. Was a cardiac catheterization completed

Section I: STUDY DRUG INFORMATION

I1. Has the patient stopped taking the study drug **permanently** since the last study visit?

YES .....1 **Complete Form S203**

NO 2

NOT APPLICABLE (already reported) ..... -1 **(J1)**

STOPDRUG	I1. Has patient stopped taking study drug permanently

I2. Was dose taken equal to dose prescribed?
(Note: "NO" should only be answered for those patients that did not receive the prescribed dose ≥5 days. Please see QxQ for further instructions.)

YES .....1 **(J1)**

NO 2

DOSECFRX	[Added version E]I2. Was dose taken equal to dose prescribed?

a. If NO, please specify the actual dosage taken and the number of days it was received. (Example: .1 mg/kg BID ordered=.3mg/kg BID X 6 days was received by patient)

DOSECFRX_S	[Added version E]I2a. Specify actual dose taken and no. of days it was taken.

Section J: ANATOMY

If Study Visit 6 (Age 14 mo.), is there any new information in the record that indicates a change to the neonatal primary anatomic diagnosis recorded on Form S101 (question B1)?

YES..... 1

NO ..... 2 **(END)**

FANATDX	J1. Information that indicates a change to diagnosis

J2. New primary anatomic diagnosis

Primary Anatomic Diagnosis Code (See Code List A) [code required for data entry]	**Primary Anatomic Diagnosis Name Worksheet**
	If coding = A4 you **must** specify here:
a. Level 1 ___ ___	a.
b. Level 2 ___ ___	b.
	If coding = A1-06-03 you **must** specify here:
c. Level 3 ___ ___	c.
d. Level 4 ___ ___	d.
e. Level 5 ___ ___	e.

fanat_dx	<created var> New primary anatomic diagnosis (Code List A)
FANATD_S	J2.1. Primary Anatomic Diagnosis Name Worksheet